

In addition, please add the following new claims 51-54:

51. (new) A stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being biased to unroll from a contracted condition to an enlarged condition; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements being biased to expand from a peripherally contracted condition to facilitate placement in a delivery device in the contracted condition and a peripherally expanded condition to facilitate expansion of the coiled-up sheet to the enlarged condition upon deployment from the delivery device.

52. (new) The stent of claim 51, wherein the coiled-up sheet comprises a shape memory alloy having a transition temperature such that the stretchable elements may be substantially plastically deformed into the peripherally contracted condition at a substantially ambient temperature and become biased towards the peripherally expanded condition when exposed to body temperature.

53. (new) The method of claim 31, wherein the constraining step comprises loading the stent onto a delivery device.

54. (new) The method of claim 31, wherein the constraining step comprises plastically deforming the sheet until the stretchable elements assume the unstretched condition.

REMARKS

In response to the Office Action mailed October 11, 2000, claims 4, and 46-50 have been canceled without prejudice, claims 1, 2, 16, 31, and 44 have been amended, and new claims 51-54 have been added, in order to more particularly and distinctly set forth the patentable subject matter of the present invention.

In the Office Action, the Examiner objected to the specification, for failing to refer to the co-pending parent application and because of the length of the Abstract. In addition, claims 1-24, 29, 30, 44-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,441,515 (“the Khosravi et al. reference”), and claims 31-42 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,042,605 (“the Martin et al. reference”). Claims 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Khosravi et al. reference in view of U.S. Patent No. 6,086,610 (“the Duerig et al. reference”), claim 28 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Khosravi et al. reference in view of U.S. Patent No. 5,649,952 (“the Lam reference”), claims 46-50 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Khosravi et al. reference in view of U.S. Patent No. 5,954,743 (“the Jang reference”), and claim 43 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Martin et al. reference in view of the Khosravi et al. reference.

Because none of the cited references, either alone or in combination, discloses, teaches or suggests the subject matter of the present claims, as amended, reconsideration and withdrawal of the rejections is respectfully requested.

First, with respect to objections to the specification, reference to the co-pending parent application has been added after the title. In addition, a new Abstract has been provided.

Turning to the § 102(b) and § 103(a) rejections, the Khosravi et al. reference discloses a stent that includes a flat sheet 10 having a mesh pattern formed therein. (Col. 3, lines 5-7). The stent

assumes a spiral shape when the sheet is rolled up into both a reduced diameter form and an expanded diameter form. (Col. 4, lines 11-16). Although the Khosravi et al. reference discloses that the stent may be formed from a self-expanding material, e.g., a shape memory material, such as Nitinol, the Khosravi et al. reference does not teach or suggest that the mesh pattern is expandable between an unstretched or peripherally contracted condition to facilitate placement in a delivery device in the contracted condition, and a stretched or peripherally expanded condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device, as presently claimed.

Turning to the present claims, claim 1 recites a stent that includes a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, and defining a periphery, the coiled-up sheet being unrollable between a contracted condition and one or more enlarged conditions, and a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements being expandable about the periphery between an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device.

As explained between page 8, line 10 and page 10, line 20, a stent in accordance with the present invention has two properties that contribute to its expansion upon deployment. First, the coiled-sheet may at least partially unroll, and the stretchable elements may expand to the stretched condition, unlike the stent disclosed in the Khosravi et al. reference. Accordingly, claim 1 and its dependent claims are neither anticipated nor otherwise obvious in light of the Khosravi et al. reference.

For similar reasons, claim 16, which also recite a stent that includes a coiled-up sheet that is expandable between a contracted condition and one or more enlarged conditions, and a plurality of stretchable elements formed in the coiled-up sheet is also not anticipated by the Khosravi et al. reference. In addition, claim 16 recites that the stretchable elements have a shape memory biased to expand about the periphery from an unstretched condition towards a stretched condition when exposed to a predetermined temperature, a feature which is not disclosed, taught, nor suggested by the Khosravi et al. reference. Accordingly, claim 16 and its dependent claims are neither anticipated nor otherwise obvious in light of the Khosravi et al. reference.

For similar reasons, claim 44 and its dependent claim are also neither anticipated nor otherwise obvious in light of the Khosravi et al. reference. Further, these same reasons support that new claim 51 and its dependent claim are neither anticipated nor otherwise obvious in light of the Khosravi et al. reference.

Turning to the other cited references, the Duerig et al. reference does not teach or suggest anything about coiled-sheet stents, and therefore may not be properly combined with the Khosravi et al. reference to make the present claims obvious. In contrast to the coiled-sheet stent disclosed in Khosravi et al., the Duerig et al. reference discloses a stent graft device 8 that includes an enclosed tubular stent sleeve 12 that has a plurality of openings 4 formed therein. (Col. 6, lines 52-57. The openings 4 in the stent sleeve 12 are compressed to a deformed configuration, whereupon the stent sleeve 12 is placed within a sleeve restraint 14. (Col. 7, lines 1-20). The resulting device 8 is delivered into a blood vessel and expanded using an inflatable balloon 18, thereby plastically deforming the restraint 14, while the stent sleeve 12 elastically recovers. (Col. 7, lines 27-36). Thus, the Duerig et al. reference discloses a composite stent graft device that, in its delivery state, is not biased to expand, but requires use of a balloon to expand the device.

In addition, the method of compressing a tubular stent as disclosed in the Duerig et al. reference runs contrary to the method of using a traditional coiled-sheet stent, such as that disclosed in the Khosravi et al. reference. With traditional coiled-sheet stents, there is no motivation or need to compress the lattice, because the coiled-sheet may simply be rolled to a desired delivery size. In contrast, the only way to radially contract an enclosed tubular stent is to compress the openings in the tube. Because of these contradictory modes of operation, there is no motivation to combine the two references. Accordingly, the Khosravi et al. and the Duerig et al. references may not be properly combined to make the present claims obvious.

For similar reasons, the Lam reference may not be properly combined with the Khosravi et al. reference to make the present claims obvious. The Lam reference merely discloses a tubular stent that is plastically deformable, and does not teach or suggest anything about coiled-sheet stents, nor a coiled-sheet stent including stretchable elements formed therein, as presently claimed.

Turning to the Jang reference, this reference also fails to teach or suggest anything about coiled-sheet stents, and, in particular, about coiled-sheet stents having stretchable elements formed therein, as presently claimed. Accordingly, the Jang reference fails to provide any additional teaching or suggestion to make the present claims obvious.

Finally, turning to the Martin et al. reference, a stent-graft 2 is disclosed that includes a thin-walled tube or graft member 4, a stent member 6, and a coupling member 6 for coupling the stent and graft members together. (Col. 5, lines 33-37). The stent member is a wire that is helically formed into a cylinder or a length of tubing. (Col. 9, line 64 through col. 10, line 5). Although the Martin et al. reference discloses that the stent member may be formed from a superelastic alloy, such as Nitinol (col. 11, lines 1-17), the Martin et al. reference does not teach or suggest anything about coiled-sheet stents, and, in particular, does not teach or suggest a coiled-sheet stent that both unrolls

and has stretchable elements that may be expanded to facilitate expansion of the coiled-sheet stent, as claimed.

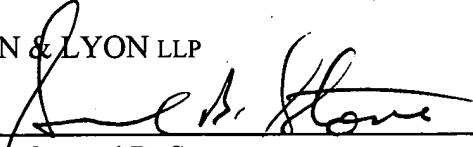
Further, with respect to claim 31, the Martin et al. reference does not disclose a method for making a coiled-sheet stent, as claimed. Claim 31 recites providing a substantially flat sheet defining a length and a width, forming a plurality of stretchable elements in the sheet, the stretchable elements being expandable along the width of the sheet between an unstretched condition and a stretched condition, rolling the flat sheet about the width into a coiled-up sheet having overlapping inner and outer longitudinal sections, and constraining the coiled-up sheet with the stretchable elements in the unstretched condition.

In contrast, in FIGS. 15A-15F, the Martin et al. reference merely discloses methods for folding a stent graft 2. Further, the stent member disclosed in the Martin et al. reference is not a coiled-up sheet, but a helically wound wire. Thus, the Martin et al. reference fails to teach or suggest providing a substantially flat sheet nor forming stretchable elements in the sheet, but instead discloses providing a tubular stent graft. Finally, the Martin et al. reference does not teach or suggest rolling the sheet into a coiled-up sheet, nor constraining the coiled-up sheet with the stretchable elements in the unstretched condition. Accordingly, claim 31 and its dependent claims are neither anticipated nor otherwise obvious in light of the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

LYON & LYON LLP

By 

Samuel B. Stone

Reg. No. 19,297

Attorneys for Applicants

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633 West Fifth Street  
Suite 4700  
Los Angeles, CA 90071-2066  
(949) 567-2300